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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,418	08/03/2001	David B. Masters	45795.23.1	8113

22859 7590 06/10/2009

INTELLECTUAL PROPERTY GROUP
FREDRIKSON & BYRON, P.A.
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	**PAPER NUMBER**
1616	
MAIL DATE	**DELIVERY MODE**
06/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/922,418	MASTERS, DAVID B.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-98,133,134 and 136-168* is/are pending in the application.

4a) Of the above claim(s) *4,8-10,18-49,53,57-59,67-98,133,134 and 136-168* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3,5-7,11-17,50-52,54-56 and 60-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-98, 133, 134 and 136-168 are pending. Claims 1-3, 5-7, 11-17, 50-52, 54-56 and 60-66 are currently under examination. Claims 4, 8-10, 18-49, 53, 57-59, 67-98, 133, 134 and 136-168 are withdrawn as being drawn to non-elected invention.

Withdrawn rejections

Applicant's amendments and arguments filed 3/25/2009 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below are herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-7, 11-17, 50-52, 54-56 and 60-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dinh et al. (US 5,510,077) in view of Greatbach (4,405,311) and in further view of Keusch et al. (US 4,706,680).

Applicant's Invention

Applicant claims a drug delivery device comprising one or more polymers, conductive materials, pharmacologically active agents and solvents which form a

cohesive body and has a solvent content of about 10% to 60%. The proteins may be selected from fibrinogen and thrombin. The solvents may be selected from water, DMSO, alcohols, acids, oils or glycols which are biocompatible. The polymer is selected from silicones, polyurethane and polylactic acid. The conductive materials are selected from gold, silver, aluminum and copper. A crosslinking agent selected from glutaraldehyde maybe added.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Dinh et al. teaches a stent comprising fibrin that is molded by compression for implantation in a human (abstract; column 3, lines 1-3). The fibrin is generated by crosslinking action of thrombin on fibrinogen (column 3, lines 59-67). The shape is provided by molding. The stent is made of a porous polymeric sheet into which fibrin is incorporated by applying by a solvent water (column 5, lines 34-64). Drugs may be incorporated into the stent and include anticoagulants, anti-inflammatory agents (column 6, lines 4-13). Glutaraldehyde may be added to increase stability as a fixing agent (crosslinking agent) (column 4, lines 54-56).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Dinh et al. do not teach a conductive material. It is for this reason that Greatbach is joined.

Greatbach teaches a method for treating arthritis by injection of electrically charged gold ions by a source of a direct current (abstract). The gold alloy may

additionally contain palladium, platinum and zinc (column 3, lines 5-13). The apparatus is housed in a reaction-free material that is implantable in the body of a human (column 2, lines 26-29). Gold is administered as an alloy for the treatment of arthritis (column 1, lines 7-10).

Dinh et al. do not teach that the current released drug delivery device has a solvent content of about 10% to 60%. It is for this reason that Keusch et al. is joined.

Keusch et al. teach conductive adhesive medical electrode assemblies comprising a conductive viscoelastic hydrophilic gel which is a homogeneous aqueous mixture, substantially free of unbound water (abstract). The gel does not bleed free water under the influence of pressure or temperature and is resistant to drying out (column 5, lines 25-40). The electrodes contain a high water content to preclude the necessity of preparatory skin shavings (column 10, line 67 through column 11, line 2). The product will withstand loss of water with a force of about 20 psi on a single surface and has a resilient memory which permits it to return to and retain its original form, unlike other gels which exude water under the influence of gravity (column 11, lines 50-57). Additionally, the hydrogel has adhesive properties which permit the hydrogel to be removed from the skin without pain or skin damage (column 11, lines 4-25).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Dinh et al., Greatbach and Keusch et al. to further include a conductive material, specifically gold alloy. One would have been motivated

to include gold alloy because Greatbach teaches that gold is a pharmacologically active ingredient used for the treatment of arthritis. Therefore, one would have been motivated to use gold as a conductive material in the drug delivery device taught by Dinh et al. because Greatbach teaches that gold can be housed in a reaction free material implantable into a human.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Dinh et al., Greatbach and Keusch et al. to form a current released drug delivery system having a solvent content of about 10-60%. One would have been motivated to manipulate the solvent content during routine experimentation to discover the optimum or workable range because Keusch et al. teach that hydrogel electrodes which withstand loss of water are desirable. Keusch et al. teach that electrodes which contain high water content prevent the need for skin shavings and have adhesive properties which permit the device to be removed without pain or skin damage. Hence, one would be motivated to optimize the solvent content in a current drug delivery device order to improve the products adhesiveness and durability.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan
Patent Examiner
Art Unit 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616